IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
TEXARKANA DIVISION

KAREN RICHARDS	§	
	§	
Plaintiff,	§	
	§	
	§	**Civil Action No._____**
	§	
v.	§	
	§	
ETHICON INC. and JOHNSON & JOHNSON	§	**JURY TRIAL DEMANDED**
	§	
	§	
	§	
Defendants.	§	

COMPLAINT FOR DAMAGES AND JURY DEMAND

Plaintiff KAREN RICHARDS ("Plaintiff") files this Complaint and for causes of action against Defendants, ETHICON, INC., and JOHNSON & JOHNSON ("Ethicon Defendants"), and alleges as follows:

JURISDICTION AND VENUE

1. The Court has jurisdiction over this civil action pursuant to 28 U.S.C. § 1332(a) inasmuch as the amount in controversy exceeds $75,000 and the Plaintiff is a citizen of a different state than one or more of the Defendants.

2. At all times material hereto, Defendants were engaged in the business of developing, manufacturing, licensing, promoting, marketing, distributing, testing, warranting and/or selling in interstate commerce throughout the United States, including Texas, either directly or indirectly, medical devices intended to treat stress urinary incontinence and/or pelvic organ prolapse, including the Ethicon Gynecare TVT-O ("Pelvic Mesh Product") that was implanted in Plaintiff in Texarkana, Texas.

3. Venue in this district for pretrial proceedings in these civil actions is proper under 28 U.S.C. § 1391, inasmuch as a substantial part of the events or omissions giving rise to the claim occurred in this district. Specifically, Plaintiff was implanted with the product at issue at the Texarkana Surgery Center in this district and was injured in this district.

4. Defendants are subject to *in personam* jurisdiction in the U.S. District Court for the Eastern District of Texas because Defendants placed defective products in the stream of commerce and all or some of those products were implanted into and caused personal injuries to Plaintiff, a Texas resident, in the State of Texas. Each Defendant has sufficient minimum contacts in Texas or otherwise intentionally avails itself of the Texas market through, without limitation, its advertisement, promotion, marketing, sales and/or distribution and other business activities, so as to render the exercise of jurisdiction over it by the Texas courts consistent with traditional notions of fair play and substantial justice.

PARTIES

5. Plaintiff KAREN RICHARDS is a citizen and resident of Arkansas who was implanted with Defendants' defective medical device at the Texarkana Surgery Center in Texarkana, Texas.

6. Defendant Ethicon, Inc. ("Ethicon") is a wholly owned subsidiary of Defendant Johnson & Johnson with its corporate headquarters in Somerville, New Jersey. Defendant Ethicon is a foreign corporation licensed to do business in the State of Texas and may be served with process by serving its registered agent, CT Corp. System, 1999 Bryan St., Ste. 900, Dallas, Texas, 75201-3136. Defendant Ethicon is a wholly owned subsidiary of Defendant Johnson & Johnson.

7. Defendant Johnson & Johnson (sometimes referred to herein as "J&J") is a New Jersey corporation that has its principal place of business located at One Johnson & Johnson Plaza,

New Brunswick, Middlesex County, New Jersey. Defendant Johnson & Johnson does business in the State of Texas and may be served with process by serving its registered agent at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey.

8. According to its website, Johnson & Johnson is the world's largest and most diverse medical and diagnostics company, with its worldwide headquarters located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. J&J organizes its subsidiary businesses into individual Business Units to coordinate the development, manufacture, testing, marketing, promotion, training, distribution, and sale of its' pelvic floor repair products, including the product at issue herein. Within J&J there are three business segments, medical devices, pharmaceutical, and consumer. Within the medical devices segment are "Business Units," including the "Ethicon Franchise." The Ethicon Franchise was charged by J&J with the design, development, promotion, marketing, testing, training, distribution, and sale of the product at issue in this case. The Chairman for the Ethicon Franchise is employed by J&J. The companies which comprise the Ethicon Franchise are thus controlled and managed by J&J and include, but are not limited to Ethicon, Inc.

9. J&J has direct or constructive possession or control of Ethicon's assets and decision-making. Acting through its business units which make up its Medical Devices business segment, including Ethicon, Inc., J&J was involved in the continued research, development, testing, manufacture, production, marketing, promotion, distribution and/or sale of medical devices including the TVT-O device at issue in this case.

10. J&J is a holding company, the purpose of which is (1) to coordinate the administration, finances, and activities of its subsidiary companies and business units including Ethicon, Inc.; (2) to act as manager; and (3) to direct or coordinate the management of its subsidiary companies and business unites or of the business, property, and estates of any subsidiary company

and business units, including Ethicon, Inc.

11. The website on which the pelvic repair mesh products are or were listed, described, and marketed, including the product at issue in this case, has at all times been maintained and operated by J&J. See https://www.jnjmedicaldevices.com/en-US/companies/ethicon/products (last viewed 7/20/2021).

12. The financial accounts of the Ethicon, Inc. business unit are consolidated within those of J&J. Ethicon's assets and properties are controlled by J&J.

13. J&J is the owner of 100% of the shares of Ethicon, Inc. stock and assets, including the rights to Ethicon, Inc.'s patents and intellectual property. J&J has control over Ethicon Inc.'s activities, operations, and policies.

14. Ethicon, Inc. acts solely as agent for J&J and Ethicon, Inc.'s policies and business operations and decisions have been controlled by J&J. J&J and Ethicon combine their property and labor in a joint venture, enterprise, or undertaking for profit, with rights of mutual control.

15. J&J is liable for any acts and/or omissions by or through Ethicon, Inc. Ethicon, Inc. is organized and controlled, and its business is conducted in such a manner as to make it merely an agent, alter ego, or business conduit of J&J. J&J has not dealt with Ethicon, Inc. at arms-length but instead has dominated and controlled Ethicon, Inc.'s activities, policies, and decisions. For example, J&J has made the decision to restructure the Medical Devices business segment to which the Ethicon business unit belongs as a streamlining and cost-savings measure. J&J's restructuring of the Medical Devices business segment resulted in a decrease or discontinuation of investment and research and development with respect to pelvic mesh and other surgical mesh devices and elimination of a sizeable portion of the workforce within the Medical Devices business segment, including many at Ethicon, Inc.

16. J&J has mingled the accounts, records, and property of Ethicon with its own. J&J has held itself out to the public as one entity with business unit/division Ethicon, Inc. J&J has expressly or impliedly assumed Ethicon's liabilities, including liabilities associated with the pelvic mesh product implanted in Plaintiff. J&J insures Ethicon, Inc. and its other business units against product liability claims through a wholly owned, captive insurance company. J&J has paid Ethicon, Inc.'s debts and expenses. Because Ethicon, Inc.'s assets and capital are subject to the ownership and control of J&J, and because the corporate form of Ethicon, Inc. has been disregarded and abused by J&J, Ethicon, Inc. is undercapitalized and the failure to disregard Ethicon, Inc.'s corporate form would result in the inequitable and unjust result that Plaintiff may be unable to satisfy any judgment ultimately obtained against Ethicon, Inc. By assuming Ethicon, Inc.'s liabilities, disregarding Ethicon, Inc's corporate form, and by taking affirmative actions to deplete the assets of Ethicon, J&J has promoted a fraud or injustice on Plaintiff.

17. J&J, directly and/or through the actions of its agent and business Ethicon, Inc., has at all pertinent times been responsible for the research, design, development, testing, manufacture, production, marketing, promotion, labeling, distribution, and/or sale of the TVT-O product at issue in this civil action.

18. Defendants are individually, jointly, and severally liable to Plaintiffs for damages suffered by Plaintiff arising from the Defendants' design, manufacture marketing, labeling, distribution, and sale if their TVT-O product at issue in the instant suit, effectuated directly and indirectly though their respective agents, servants, employees, and/or owners, all acting within the course and scope of their respective agencies, services, employments, and/or ownership.

19. To the extent that Ethicon is claimed to maintain any separate corporate identify from J&J, the corporate identify of Ethicon should be pierced so that Ethicon's assets and liabilities

are considered the assets and liabilities of J&J, and J&J should be held liable in the same manner as Ethicon, Inc. for any and all of Plaintiff's injuries and damages.

20. Defendants are vicariously liable for the acts and omissions of their employees and/or agents who were at all times relevant hereto acting on behalf of Defendants and within the scope of their employment or agency with Defendants.

21. At all times relevant herein, Defendants were engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, testing, training, marketing, promoting, packaging, labeling, and /or selling such devices, including the TVT-O. Defendants manufacture, market, advertise, promote, and sell products worldwide.

22. Johnson & Johnson and Ethicon Inc. are collectively referred to herein as "Defendants," "Ethicon Defendants," or "Ethicon."

FACTUAL BACKGROUND

The Pelvic Mesh Product

23. At all times relevant herein, Defendants were engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, marketing, packaging, labeling, and selling such devices, including the GYNECARE TVT-O (the "TVT-O"), the product at issue in this case, sometimes referred to herein as the "Pelvic Mesh Product."

24. Defendants' Pelvic Mesh Products are products targeted at women who suffer from pain, discomfort, and stress urinary incontinence as a result of weakening or damage to the walls of the vagina. The Pelvic Mesh Products are represented by Defendants to correct and restore normal vaginal structure by implantation of polypropylene mesh in the vaginal wall tethered in place by two arms that extend up through the buttocks or to prevent stress urinary incontinence by implantation of a strip of mesh under the urethra for support. The Pelvic Mesh Products were and

are specifically promoted to physicians and patients as an innovative, minimally invasive procedure with minimal local tissue reactions, minimal tissue trauma, and minimal pain while correcting stress urinary incontinence and pelvic organ prolapse.

25. Prior the implantation of the Pelvic Mesh Product at issue in this claim, Defendants sought and obtained Food and Drug Administration ("FDA") approval to market the Pelvic Mesh Product under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required.

26. Despite claims that the monofilament polypropylene mesh in the Pelvic Mesh Products, including the TVT-O, is inert, the scientific evidence shows that this material is biologically incompatible with human tissue and promotes an immune response. This immune response promotes degradation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh. Certain information was available in the medical literature regarding the dangers of polypropylene mesh and manufacturers should have been aware of this literature.

a. Shrinkage and bacteria lead to an evolving process and increased erosion (Klinge U. Eur J Surg 1998; 164:965, Jacquetin B. Int Urogyn J 2009; 20:893, Tunn R. Ultrasound Obstetrics Gynecol 2007; 29:449).

b. Polypropylene mesh has long been known to shrink (Klinge U. Eur J Surg 1998; 164:965, Jacquetin B. Int Urogyn J 2009; 20:893, Tunn R. Ultrasound Obstetrics Gynecol 2007; 29:449). By 1998, polypropylene mesh was known to shrink 30-50%. This was subsequently confirmed in 2007 (Klinge U. Eur J Surg 1998; 164:965, Jacquetin B. Int Urogyn J 2009; 20:893, Tunn

R. Ultrasound Obstetrics Gynecol 2007; 29:449). Predominate infection/inflammation was noted in 2007 in explanted polypropylene samples (Yahi Y. Int Urogyn J 2007; 18(Suppl 1):S149).

c. The weave of the mesh produces very small interstices which allow bacteria to enter and to hide from the host defenses designed to eliminate them. The bacteria can secrete an encasing slime (biofilm) which further serves to protect them from destruction by white blood cells and macrophages (Osterberg B. ActaChirScand1979; 145:431, Merritt K. J BiomatAppl 1991; 5:185, An Y. J Biomed Mater Res (ApplBiomat) 1998; 43:338).

d. The large surface area promotes wicking of fluids and bacteria which provides a safe haven for bacteria which attach themselves to the mesh during the insertion process (Mahmoud W. J Biomat Sci Polymer Ed 1996; 7:751, Klinge U. J Biomed Mater Res 2002; 63:765, Vollebregt A. Int Urogyn J 2009; 20:1345).

e. The size of the mesh placed equates to a large surface area with many places for bacteria to hide while being protected from host defenses (Mahmoud W. J Biomat Sci Polymer Ed 1996; 7:751, Klinge U. J Biomed Mater Res 2002; 63:765, Vollebregt A. Int Urogyn J 2009; 20:1345).

f. Polypropylene is impure: There is no such thing as pure polypropylene. Polypropylene contains about 15 additional compounds which are leached from the polypropylene and are toxic to tissue which enhances the inflammatory reaction and the intensity of fibrosis (Sternschuss G. J Urol

2012; May 12 epub, Frostling H. Scand J Work Environ Health 1984; 10:163).

g. Prolene (polypropylene) was shown to be not inert in 1986 and again in 2003 with flaking and fissuring demonstrated by scanning electron microscopy which leads to degradation and release of toxic compounds. This enhances the inflammatory and fibrotic reactions (Coda A. Hernia 2003; 7:29, Jongebloed WL. Doc Ophthalmol 1986; 64:143–52).

h. With the loss of polypropylene due to degradation, the surface area is greatly increased thus providing greater areas for bacterial adherence and more elution of toxic compounds from the polypropylene and also the freed toxic polypropylene itself, all of which increases the inflammatory reaction and intensity of fibrosis (Jongebloed W. Doc Ophth 1986; 64:143, Sternschuss G. J Urol 2012; May 12 epub, Clave A. Int Urogyn J 2010; 21:261).

i. Complications from mesh placement for pelvic organ prolapse include among other adverse events: acute and chronic infection, tissue contraction due to mesh shrinkage, erosion of the mesh into adjacent structures, and dyspareunia [painful sexual intercourse]. Cosson, M., et al., Mechanical properties of synthetic implants used in the repair of prolapse and urinary incontinence in women: which is the ideal material? Int Urogynecol J Pelvic Floor Dysfunct, 2003. 14(3): p. 169-78; discussion 178. Jones, K.A., et al., Tensile properties of commonly used prolapse meshes. Int Urogynecol J Pelvic Floor Dysfunct, 2009. 20(7): p. 847-53. Margulies, R.U., et al.,

Complications requiring reoperation following vaginal mesh kit procedures for prolapse. Am J Obstet Gynecol, 2008. 199(6): p. 678 e1-4.

j. Erosion can be defined as the mesh wearing, or slowly grinding through the vaginal wall. This is a serious complication and moreover, there is evidence that meshes shrink in vivo leading to increased stiffness, pain and poor restoration of the normal properties of the vagina. Dora, C.D., et al., Time dependent variations in biomechanical properties of cadaveric fascia, porcine dermis, porcine small intestine submucosa, polypropylene mesh and autologous fascia in the rabbit model: implications for sling surgery. J Urol, 2004. 171(5): p. 1970-3.

k. Larger pores within polypropylene mesh materials, allowing macrophage and leukocyte migration, reduce infection. Birch C, Fynes MM. The role of synthetic and biological prosthesis in reconstructive pelvic floor surgery. Curr Opin Obstet Gynecol. 2002; 14:527–595. 22. Govier FE, Kobashi KC, Kozlowski PM, Kuznetsov DD, Begley SJ, McGonigle KF, et al. High complication rate identified in sacrocolpopexy patients attributed to silicone mesh. J Urol. 2005;65:1099–1103.

27. Despite claims that the monofilament polypropylene mesh in the Pelvic Mesh Product is inert, the scientific evidence shows that this material is biologically incompatible with human tissue and promotes an immune response. This immune response promotes degradation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh.

28. The Pelvic Mesh Product has been and continues to be marketed to the medical community and to patients as a safe, effective, and reliable medical device that can be implanted

by safe, effective, and minimally invasive surgical techniques.

29. Defendants marketed and sold the Pelvic Mesh Products, including the TVT-O, through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies included, but are not limited to, aggressive marketing and the provision of valuable cash and non-cash benefits to healthcare providers. Defendants also utilized documents, patient brochures, and websites, offering exaggerated and misleading expectations as to the safety and utility of this product.

30. Contrary to the representations and marketing of Defendants, the Pelvic Mesh Products, including the TVT-O, have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating revision surgeries, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff Karen Richards. The defects stem from many issues, including:

a. the use of polypropylene material in the Pelvic Mesh Product and the immune reaction that results;

b. the design of the Pelvic Mesh Product to be inserted transvaginally into an area of the body with high levels of pathogens that adhere to the mesh, which can cause immune reactions and subsequent tissue breakdown;

c. the contraction or shrinkage of the mesh;

d. biomechanical issues with the design of the mesh that create strong amounts of friction between the mesh and the underlying tissue that subsequently cause that tissue to degrade;

e. degradation of the mesh itself over time which causes the internal tissue to degrade;

f. the welding of the mesh itself during production, which creates a toxic substance that contributes to the degradation of the mesh and host tissue; and

g. the design of the trocars (devices used to insert the Pelvic Mesh Product into the vagina) requires tissue penetration in nerve-rich environments, which results frequently in the destruction of nerve endings.

31. Pelvic mesh products used for the surgical management of stress urinary incontinence (SUI) in women are primarily two different designs: the transobturator sling (frequently referred to as a TOT or TVT-O and the type of product at issue in this case) and the retropubic sling (frequently referred to as a TVT). The transobturator sling passes through the obturator space into the thigh, while the retropubic sling hammocks the urethra and exits up and out behind the pubic bone. In 2006, Defendants also began selling a "mini-sling," named the TVT-Secur, which was a shorter sling anchored directly to either the retropubic fascia (the "U method") or the obturator internus muscle (the "H method").

32. Transobturator slings cause nerve injuries, including obturator neuralgia, pudendal neuralgia, ilioinguinal neuralgia, and Complex Regional Pain Syndrome Type 2. These diagnoses are known for their disabling vaginal pain what makes sexual intercourse impossible, pelvic and extrapelvic pain that reduces mobility to a sedentary level, and bowel and bladder dysfunction that may include an inability to evacuate the bowels and bladder associated with severe anorectal pain.

33. Upon information and belief, Defendants have consistently underreported and withheld information about the propensity of their Pelvic Mesh Products, including the TVT-O and its predicate devices, to fail and cause injury and complications, and have misrepresented the efficacy and safety of these products, through various means and media, actively and intentionally

misleading the public.

34. Despite the chronic underreporting of adverse events associated with the Pelvic Mesh Products, enough complaints were recorded for the Food and Drug Administration ("FDA") to issue a public health notification regarding the dangers of these devices.

35. On October 20, 2008, the FDA issued a Public Health Notification that described over a thousand (1,000) complaints (otherwise known as "adverse events") that had been reported over a three-year period relating to the Pelvic Mesh Products and other similar products. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that Defendants are some of the manufacturers of the products that are the subject of the notification.

36. On July 13, 2011, the FDA issued a Safety Communication entitled, "UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse." Therein, the FDA advised that it had conducted an updated analysis of adverse events reported to the FDA and complications reported in the scientific literature and concluded that surgical mesh used in transvaginal repair of pelvic organ prolapse was an area of **"continuing serious concern"** (emphasis added). The FDA concluded that serious complications associated with surgical mesh for transvaginal repair of pelvic organ prolapse were "not rare." These serious complications include, but are not limited to, neuromuscular problems, vaginal scarring/shrinkage, and emotional problems. Many of the serious complications required medical and surgical treatment and hospitalization. The FDA concluded that it was not clear that transvaginal repair of pelvic organ prolapse and stress urinary incontinence with mesh-kits was more effective than traditional non-mesh repair of these conditions. The FDA conducted a systematic review of the published scientific literature from 1996 to 2011 and

concluded that transvaginal pelvic organ prolapse repair with mesh "does not improve symptomatic results or quality of life over traditional non mesh repair." In the July 13, 2011, Safety Communication, the FDA concluded that "a mesh procedure may put the patient at risk for requiring additional surgery or for the development new complications. Removal of the mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life. Complete removal of mesh may not be possible." The information contained in the FDA's Public Health Notification of October 2008 and the FDA Safety Communication of July 13, 2011, was known or knowable to Defendants and was not disclosed in any manner.

37. Defendants have further known the following:

a. that some of the predicate devices for the Pelvic Mesh Products had high failure and complication rates, resulting in the recall of some of these predicate devices;

b. that there were and are significant differences between the Pelvic Mesh Products and some or all of the predicate devices, rendering them unsuitable for designation as predicate devices;

c. that these significant differences render the disclosures to the FDA incomplete and misleading; and

d. that the Pelvic Mesh Product was and is causing numerous patients severe injuries and complications.

38. Defendants suppressed this information and failed to accurately and completely disseminate or share this and other critical information with others, including Plaintiff. As a result, Defendants actively and intentionally misled and continue to mislead the public into believing that

the Pelvic Mesh Products and the procedures for implantation were and are safe and effective.

39. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Pelvic Mesh Products.

40. Defendants failed to design and establish a safe, effective procedure for removal of the Pelvic Mesh Product; thus, in the event of a failure, injury, or complications, it is impossible to easily and safely remove the Pelvic Mesh Products.

41. Feasible, reasonable, and suitable alternative designs as well as reasonable suitable alternative procedures and instruments for repair of stress urinary incontinence have existed at all times relevant to this matter, including, but not limited to the following: the Burch Procedure colposuspension with delayed absorbable sutures; autologous fascia slings; an allograft sling using a product like Repliform or other biological matrix; a sling with less polypropylene such as Ultrapro; a retropubic sling; a retropubic mini-sling, such as the TFS device from TFS Surgical; a retropubic sling or retropubic mini-sling comprised of a polymer-based alternative to polypropylene, such as Polyvinylidene fluoride (PVDF); or a transobturator sling comprised of PVDF.

42. The Pelvic Mesh Products were at all times utilized and implanted in a manner foreseeable to Defendants, as they generated the instructions for use, created the procedures for implanting the device, and trained the implanting physicians.

43. Defendants provided incomplete, insufficient, and misleading training and information to physicians to increase the number of physicians utilizing the Pelvic Mesh Product, and thus increase the sales of this product.

44. The Pelvic Mesh Product implanted into Plaintiff Karen Richards was in the same or substantially similar condition as it was when it left the possession of Defendants, as

well as being in the condition directed by and expected by these Defendants.

45. Plaintiff Karen Richards and her physician foreseeably used and implanted the Pelvic Mesh Product, and did not misuse or alter this product in an unforeseeable manner.

46. The injuries, conditions, and complications suffered by women who have been implanted with the Pelvic Mesh Product include, but are not limited to, mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), allodynia, blood loss, acute and chronic nerve damage and pain, obturator nerve damage, pudendal nerve damage, pelvic floor damage, chronic pelvic and extrapelvic pain, urinary and fecal incontinence, and prolapse of organs. In many cases, these women have been forced to undergo intensive medical treatment, including, but not limited to, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and surgeries to remove portions of the female genitalia, to locate and remove mesh, and to attempt to repair pelvic organs, tissue, and nerve damage.

47. The medical and scientific literature studying the effects of polypropylene pelvic mesh (like the material used in the Pelvic Mesh Product) have examined each of these injuries, conditions, and complications and determined that they are in fact casually related to the mesh itself and do not often implicate errors related to the implantation of the device.

48. Defendants knew and had reason to know that the Pelvic Mesh Product could and would cause severe and grievous personal injury to the users of the Pelvic Mesh Product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

49. At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put the Plaintiff, her treating physicians, and the public on notice of

the dangers and adverse effects caused by implantation of the Pelvic Mesh Products.

50. The Pelvic Mesh Products were defective as marketed due to inadequate warnings, instructions, labeling, and/or inadequate testing.

51. The TVT-O is designed to be inserted into and through the obturator internus and groin muscles, placing it in proximity to the obturator nerve; Defendants failed to study or account for anatomic variations of the obturator nerve when designing the device.

52. The Pelvic Mesh Products were designed to be permanently implanted into a woman's body yet the product changes after implantation; it contracts over time which can pull or compress nerves important for sexual function, mobility, bowel function, bladder function, and chronic pelvic and nerve pain (neuralgia). This contraction over time, which can pull, and also cause fibrosis of muscles, adhesions between tissues, and inflammation which impair sexual function, impaired mobility, impaired bowel and bladder function, and chronic pelvic and extrapelvic pain, neuralgia, among other mesh-related issues.

Plaintiff's TVT-O Implantation

53. Upon information and belief, Robert G. Parham, M.D. recommended the Pelvic Mesh Product to Plaintiff Karen Richards as appropriate and safe for the treatment of stress urinary incontinence. Consequently, Plaintiff consented to the implantation of the Pelvic Mesh Product.

54. Upon information and belief, Robert G. Parham, M.D. recommended the Pelvic Mesh Product to Plaintiff as appropriate and safe for the treatment of stress urinary incontinence. Consequently, Plaintiff consented to the implantation of the Pelvic Mesh Product.

55. In June 2008, Plaintiff underwent surgery to address her stress urinary incontinence at the Texarkana Surgery Center in Texarkana, Texas. During this surgery, she was implanted with an Ethicon Gynecare TVT-O by Dr. Parham.

56. In August 2020, Plaintiff was informed that her mesh sling had eroded and surgical excision was recommended.

57. On December 7, 2020, at Mercy Hospital in St. Louis, Missouri, Plaintiff underwent surgery by Dr. Dionysios Veronikis, M.D. to excise the Gynecare TVT-O sling due to significant vaginal pain, groin pain, and dyspareunia.

58. As a direct and proximate cause of having the Gynecare TVT-O sling implanted in her, Plaintiff Karen Richards has experienced significant mental and physical pain and suffering, to include dyspareunia, disabling groin pain, vaginal pain, pelvic pain, extrapelvic pain, neuromuscular pain, abdominal pain, leg pain, back pain, dysuria, urinary frequency, urinary urgency, stress incontinence, vulvodynia, chronic bladder pain, has sustained permanent injury and scarring, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

59. Plaintiff could not have reasonably discovered her injuries and/or the occasion, manner and/or means by which Defendants' breach of duty occurred until within two years of the filing of this complaint.

60. Further, Plaintiff did not and, exercising reasonable diligence, including consultation with medical professionals, could not discover the existence of her legal cause of action or the injuries caused by Defendants' breach of duty and/or defective products until within two years of the filing of this complaint. Further, Defendants continue to deny that their products are defective or cause injuries such as those suffered by Plaintiff and Defendants continued to manufacture and sell the products at issue and/or related or predicate products. Any applicable statute of limitations has been tolled by the knowing and active concealment and denial of material

facts known by Defendants when Defendants had a duty to disclose and/or by the application of the discovery rule.

61. Neither Plaintiff nor her healthcare providers were warned that the Gynecare TVT-O device was unreasonably dangerous or of the risks of the device, outlined herein, even when used exactly as intended by Defendants. To the contrary, Defendants promoted and sold the type of transvaginal mesh device implanted in Plaintiff and thousands of women like Plaintiff, to healthcare providers as a safe alternative to other procedures that did not incorporate the Defendants' products.

62. As a direct and proximate result of being surgically implanted with Defendants' unreasonably dangerous transvaginal mesh device, the Gynecare TVT-O, Plaintiff has suffered, and continues to suffer, debilitating injuries, including but not limited to the injuries listed above and, likely, nerve pain that may be permanent. Plaintiff brings this suit for damages related to those injuries.

Defendants' Tortious Conduct

63. Defendants' TVT-O Pelvic Mesh Product was implanted in Plaintiff to treat her SUI, the use for which Defendants designed, manufactured, marketed, and/or sold this product.

64. At all times relevant to this matter, Defendants marketed their Pelvic Mesh Products (including the TVT-O Pelvic Mesh Product) to the medical community, medical device manufacturers, and patients and consumers as safe, effective, and reliable medical devices that could be implanted by safe, effective, and minimally invasive surgical techniques for the treatment of medical conditions, primarily POP and SUI, and as being safer and more effective as compared to other products and procedures for treatment of similar conditions.

65. Defendants marketed and sold their Pelvic Mesh Products (including the TVT-O Pelvic Mesh Product at issue in this case) to medical device manufacturers, the medical community at large, and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies included, without limitation, direct-to-consumer advertising including aggressive marketing to healthcare providers at medical conferences, hospitals, and private offices, and the provision of valuable consideration and benefits to healthcare providers. Defendants also utilized documents, brochures, websites, and/or telephone information lines in offering exaggerated and misleading expectations as to the safety and utility of the products.

66. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, Defendants' Pelvic Mesh Products (including the TVT-O Pelvic Mesh Product at issue in this case) have high failure rates and high injury and complication rates, fail to perform as intended, require frequent and often debilitating operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff.

67. Defendants have consistently underreported and withheld information about the propensity of the Pelvic Mesh Products (including the TVT-O Pelvic Mesh Product at issue in this case) to fail and to cause injury and complications, have misrepresented the efficacy and safety of their Pelvic Mesh Products (including the TVT-O Pelvic Mesh Product at issue in this case) through various means and media, and have actively and intentionally misled the FDA, the medical community, patients, and the public at large about those products.

68. Defendants have known at all times and had reason to know that their Pelvic Mesh Products (including the TVT-O Pelvic Mesh Product at issue in this case) were and are causing numerous patients severe injuries and complications including those suffered by Plaintiff, and that

their disclosures to the FDA were and are incomplete and misleading. Defendants suppressed this information and failed to accurately and completely disseminate or share this information and other critical information with the FDA, healthcare providers, and patients. As a result, Defendants actively and intentionally misled and continue to mislead the public, including the medical community, healthcare providers, and patients, including Plaintiff and her doctor into believing that their Pelvic Mesh Products were and are safe and effective, which led to the prescribing and implantation of the TVT-O Pelvic Mesh Product into Plaintiff.

69. Defendants individually and/or jointly failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Pelvic Mesh Products (including the TVT-O Pelvic Mesh Product at issue in this case).

70. Knowing the significant risk that the Pelvic Mesh Products (including the TVT-O Pelvic Mesh Product at issue in this case) would fail and/or imperil the health and welfare of the women in which they were implanted, Defendants failed to properly design the Pelvic Mesh Products or to establish a safe, effective procedure for the removal of the Pelvic Mesh Products, rendering it impossible to safely or easily remove the Pelvic Mesh Products leading to foreseeable injuries to patients, including Plaintiff.

71. Feasible and suitable alternative designs and products, as compared to Defendants' Pelvic Mesh Products (including the TVT-O Pelvic Mesh Product at issue in this case) as well as suitable alternative procedures and instruments for implantation and treatment of stress urinary incontinence, pelvic organ prolapse, and other similar conditions, have existed at all relevant times, including, but not limited to the following examples: the Burch Procedure colposuspension with delayed absorbable sutures; autologous fascia slings; an allograft sling using a product like Repliform or other biological matrix; a sling with less polypropylene such as Ultrapro; a retropubic

sling; a retropubic mini-sling, such as the TFS device from TFS Surgical; a retropubic sling or retropubic mini-sling comprised of a polymer-based alternative to polypropylene, such as Polyvinylidene fluoride (PVDF); or a transobturator sling comprised of PVDF.

72. The Pelvic Mesh Products (including the TVT-O Pelvic Mesh Product at issue in this case) were at all times utilized and implanted in a manner foreseeable to Defendants including the implantation of Plaintiff's TVT-O Pelvic Mesh Product.

73. Defendants have provided incomplete, insufficient, and misleading training and information to physicians in order to increase the number of physicians utilizing the Pelvic Mesh Products (including the TVT-O Pelvic Mesh Product at issue in this case), and thus increase the sales of the Pelvic Mesh Products. This has led to the dissemination of inadequate and misleading information to doctors and patients, including Plaintiff and her physicians.

74. The TVT-O Pelvic Mesh Product implanted into Plaintiff was in the same or substantially similar condition as it was when it left the possession of Defendants, and in the condition directed by and expected by Defendants.

75. The injuries, conditions, and complications, some or all of which were and/or will be reasonably expected to be suffered by Plaintiff and others due to the Pelvic Mesh Product include without limitation dyspareunia, vulvar, perineal, and/or perianal allodynia, spastic pelvic floor syndrome, pudendal neuralgia, obturator neuralgia, ilioinguinal neuralgia, pelvic pain, extrapelvic pain, groin pain, vaginal pain, inner thigh pain, paresthesia, depression, and impaired bladder function, as well as other symptoms.

76. Despite knowledge of these catastrophic injuries, conditions, and complications caused by the Pelvic Mesh Products, Defendants manufactured, marketed, and sold the Pelvic Mesh Products while failing to adequately warn, label, instruct, and disseminate information with

regard to the Pelvic Mesh Products, both prior to and after the marketing and sale of the Pelvic Mesh Products.

77. On or about January 3, 2012, the FDA ordered Defendants to conduct randomized, controlled clinical testing of the Pelvic Mesh Products or be ordered to cease their manufacture, marketing, and sale.

78. On or about June 5, 2012, Defendants announced that they were withdrawing some of their Pelvic Mesh Products from the market and, as a result, would not be conducting the randomized, controlled clinical testing ordered by the FDA.

79. As of the date of the filing of Plaintiff's Complaint, Defendants have not begun or completed any of the randomized, controlled clinical testing ordered by the FDA.

80. The Gynecare TVT-O was designed to be permanently implanted into a woman's body yet the product changes after implantation: The TVT-O mesh contracts over time which, *inter alia,* can pull or compress nerves, muscles, and other soft tissues important for sexual function, mobility, bowel function, and bladder function, and can cause fibrosis of muscles, adhesions between tissues, an inflammation which impair sexual function, mobility, bowel and bladder function, and cause chronic pelvic and extrapelvic pain.

81. The risk of serious injuries was known or should have been known to Defendants, but in spite of these risks, Defendants continued to market their pelvic mesh devices, including the TVT-O Pelvic Mesh Product, for transvaginal use to physicians and patients, including Plaintiff and Plaintiff's healthcare providers, without adequate warnings.

82. Had Defendants properly and adequately disclosed the risks associated with the pelvic mesh product for transvaginal use, including the TVT-O Pelvic Mesh Product device at issue, Plaintiff would not have agreed to treatment with the device and on information and belief,

Plaintiff's implanting physician would have advised her of the risks as part of his informed consent, and/or otherwise altered his prescribing habits, such as recommending a different procedure or device or no surgical treatment.

83. The injuries suffered by Plaintiff were caused by the wrongful acts, and/or omissions, and representations of Defendants, as outlined above.

84. As a direct and proximate result of having the Gynecare TVT-O device implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury which includes or more likely than not may include any of the following: dyspareunia, disabling pelvic, groin, and vaginal pain, neuromuscular pain and damage, urinary frequency, urinary urgency, stress incontinence, vulvodynia, chronic bladder pain, has sustained permanent injury and scarring, has undergone medical treatment and will likely undergo further medical treatment and procedures and has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

COUNT I: STRICT LIABILITY – FAILURE TO WARN

85. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

86. Defendants designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the Pelvic Mesh Product at issue herein.

87. The TVT-O mesh was manufactured, designed, marketed, labeled and sold in a defective condition, for use by the Plaintiff's physicians and/or healthcare providers and all other consumers of the product, making the product unreasonably dangerous.

88. Defendants' TVT-O Pelvic Mesh Product is defective due to Defendants' failure to

adequately warn or instruct Plaintiff and/or her health care providers of subjects.

89. Set for below are the warnings, precautions, contraindications, and adverse reactions in the Instructions for Use (IFU) for the TVT-O device implanted in Plaintiff:

CONTRAINDICATIONS

As with any suspension surgery, this procedure should not be performed in pregnant patients. Additionally, because the PROLENE polypropylene mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregnancy.

WARNINGS AND PRECAUTIONS

- Do not use GYNECARE TVT Obturator procedure for patients who are on anti-coagulation therapy.
- Do not use GYNECARE TVT Obturator procedure for patients who have a urinary tract infection.
- Users should be familiar with surgical technique for urethral suspensions and should be adequately trained in the GYNECARE TVT Obturator procedure before employing the GYNECARE TVT Obturator device.
- Acceptable surgical practice should be followed for the GYNECARE TVT Obturator procedure as well as for the management of contaminated or infected wounds.
- The GYNECARE TVT Obturator procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to patient anatomy and correct passage of the device will minimize risks.
- Bleeding may occur post-operatively. Observe for any symptoms or signs before releasing the patient from hospital.
- Although bladder injury is unlikely to occur with this technique, cystoscopy may be performed at the discretion of the surgeon.
- Do not remove the plastic sheaths until the tape has been properly positioned.
- Ensure that the tape is placed with no tension under the mid-urethra.
- Do not perform this procedure if you think the surgical site may be infected or contaminated.
- Since no clinical information is available about pregnancy following sub-urethral sling procedure with the GYNECARE TVT Obturator System, the patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.
- Since no clinical information is available about vaginal delivery following a sub-urethral sling procedure with the GYNECARE TVT Obturator System, in case of pregnancy delivery via cesarean section should be considered.

- Post-operatively, the patient should be advised to refrain from heavy lifting and/or exercise (e.g., cycling, jogging) for at least three to four weeks and intercourse for one month. The patient can usually return to other normal activity after one or two weeks.
- The patient should be instructed to contact the surgeon immediately if dysuria, bleeding or other problems occur.
- Transient leg pain lasting 24–48 hours may occur and can usually be managed with mild analgesics.
- As with other incontinence procedures, de novo detrusor instability may occur following a sub-urethral sling procedure utilizing the GYNECARE TVT Obturator System. To minimize this risk, make sure to place the tape as described above.
- Do not contact the PROLENE mesh with any staples, clips or clamps as mechanical damage to the mesh may occur.
- Do not resterilize GYNECARE TVT Obturator device or its components. Discard opened, unused devices.
- Prophylactic antibiotics can be administered according to the surgeon's usual practice.

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheaths initially covering the PROLENE mesh are designed to minimize the risk of contamination.
- Over correction, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

90. In their IFU, as well as the marketing materials they prepared and disseminated to patients and healthcare providers, Defendants omitted critical information regarding the risks and potential complications of the TVT-O Pelvic Mesh Product at issue in this case. Specifically, Defendants failed to properly and adequately warn and instruct Plaintiff and her healthcare providers as to the following (subsequently referred to as the "Risks and Potential Complications"):

a. That the TVT-O was not studied prior to launch for safety and efficacy;

b. That the TVT-O has propensities to contract, retract, and/or shrink inside the body;

c. That the TVT-O has propensities for degradation, fragmentation, and/or creep;

d. That the TVT-O's inelasticity prevents proper mating with the pelvic floor and vaginal region;

e. The magnitude of the risk of mesh erosion or extrusion;

f. The risk of chronic inflammation resulting from the TVT-O;

g. The risk of chronic infections resulting from the TVT-O;

h. The risk of developing chronic regional pain syndrome as a result of chronic inflammation/infection;

i. The risk of permanent vaginal or pelvic scarring as a result of the TVT-O;

j. The risk and/or magnitude of recurrent, intractable pelvic and extrapelvic pain, groin pain, nerve pain, and other pain resulting from the TVT-O;

k. The risk of direct nerve injury to the ilioinguinal nerve;

l. The risk of secondary nerve injury or irritation to the ilioinguinal nerve;

m. The risk of direct nerve injury to the pudendal nerve;

n. The risk of secondary nerve irritation to the pudendal nerve;

o. The risk of direct nerve injury to the obturator nerve;

p. The risk of secondary nerve irritation to the obturator nerve;

q. The magnitude of the risk of dyspareunia (painful sexual intercourse) in patients;

r. That the TVT-O may result in dyspareunia that makes vaginal penetration impossible;

s. The risk of vulvar, perineal, or perianal allodynia;

t. The frequency with which the need for corrective or revision surgery to adjust or remove the TVT-O may occur in patients;

u. The magnitude of the risk of acute and long-term complications that could arise as a result of implantation of the TVT-O in patients;

v. The hazards associated with the TVT-O, including obturator, pudendal, and ilioinguinal neuralgia, permanent nerve damage, and pelvic floor and groin myalgia;

w. That treatment of SUI with the TVT-O exposes patients to greater risk than feasible available devices for SUI, including pelvic mesh products utilizing

alternative polypropylene material or non-polypropylene surgical products, alternatives, and procedures;

x. That treatment with the TVT-O makes future surgical repair more difficult than feasible available alternatives;

y. That TVT-O offers no improvement in efficacy compared to non-mesh repairs and non-mesh repairs do not place the obturator, ilioinguinal, or pudendal nerve at risk acutely or over time;

z. That use of the TVT-O puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

aa. That removal of the TVT-O due to complications may significantly impair the patient's quality of life;

bb. That complete removal of the TVT-O may not be possible;

cc. That complete removal of the TVT-O may not result in complete resolution of the complications, including pain;

dd. The foreseeable and unavoidable risk of acute obturator, pudendal, and/or ilioinguinal neuralgia or obturator, pudendal, and/or ilioinguinal neuralgia occurring months or years after implantation;

ee. The magnitude of the risk of obturator, pudendal and/or ilioinguinal neuralgia;

ff. The risk of permanent injury and pain to the muscles and soft tissues of the pelvic floor that may occur acutely after implantation or become symptomatic months or years after implantation; and

gg. That the design of the TVT-O, which involves the passage of trocar needles through the obturator internus and groin muscles, poses a risk of injury to

the pelvic and extrapelvic region greater than that of feasible available alternatives.

91. Arguing further, Defendants failed to properly and adequately warn and instruct Plaintiff and her healthcare providers as to the proper candidates for, and the safest and most effective methods of, implantation and use of Defendants' Pelvic Mesh Products, including the TVT-O Pelvic Mesh Product at issue in this case. Defendants also failed to properly and adequately warn and instruct Plaintiff and her healthcare providers with regard to the inadequate research and testing of the Pelvic Mesh Products, including the TVT-O Pelvic Mesh Product at issue in this case, and the complete lack of a safe, effective procedure for removal of the Pelvic Mesh Products.

92. The Pelvic Mesh Product at issue herein was expected to, and did, reach the intended consumers, handlers, and persons receiving the products, including Plaintiff, with no substantial change in the condition in which the products were designed, produced, manufactured, sold, distributed, labeled and marketed by Defendants.

93. The Pelvic Mesh Product at issue herein implanted in Plaintiff was not reasonably safe for its intended use and was defective as described herein as a matter of law due to its lack of appropriate and necessary warnings. Specifically, Defendants did not provide sufficient or adequate warnings regarding, among other subjects:

a. The propensities of the Pelvic Mesh Product at issue herein to contract, retract, and/or shrink inside the body;

b. The propensities of the Pelvic Mesh Product at issue herein for degradation, fragmentation, disintegration and/or creep;

c. The inelasticity of the Pelvic Mesh Product at issue preventing proper mating with the pelvic floor and vaginal region;

d. The rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Pelvic Mesh Product at issue herein;

f. The risk of chronic infections resulting from the Pelvic Mesh Product at issue herein;

g. The risk of permanent vaginal or pelvic scarring as a result of the Pelvic Mesh Product at issue herein;

h. The risk of recurrent, intractable groin pain, pelvic pain, extrapelvic pain, and other pain resulting from the Pelvic Mesh Product at issue herein;

i. The need for corrective or revision surgery to adjust or remove the Pelvic Mesh Product at issue herein;

j. The severity of complications that could arise as a result of implantation of the Pelvic Mesh Product at issue herein, including permanent nerve damage;

k. The hazards associated with the Pelvic Mesh Product at issue herein;

l. The defects of the Pelvic Mesh Product at issue as described herein;

m. Treatment of stress urinary incontinence with the Gynecare TVT-O is no more effective than feasible available alternatives;

n. Treatment of stress urinary incontinence with the Gynecare TVT-O exposes patients to greater risk than feasible available alternatives;

o. Treatment of stress urinary incontinence with the Gynecare TVT-O makes future surgical repair more difficult than feasible available alternatives;

p. Use of the Pelvic Mesh Product at issue herein puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. Removal of the Pelvic Mesh Product at issue herein due to complications may involve multiple surgeries and may significantly impair the patient's quality of life and intimate personal relationships;

r. Complete removal of the Pelvic Mesh Product at issue herein may not be possible and may not result in complete resolution of the complications, including pain; and

s. The nature, magnitude and frequency of complications that could arise as a result of implantation of the Pelvic Mesh Product at issue herein.

94. Defendants, by exercising reasonable diligence, could have made such warnings available to Plaintiff, Plaintiff's healthcare providers, and the medical community.

95. As a direct and proximate result of Defendants' failure to provide Plaintiff, Plaintiff's healthcare providers, and the medical community with sufficient or adequate warnings, Plaintiff and Plaintiff's healthcare providers were not adequately informed of the potential dangers and/or defects of the Pelvic Mesh Product at issue herein.

96. By reason of the foregoing, Plaintiff has damages in an amount in excess of the jurisdiction limits of all the lower courts which would have had jurisdiction.

97. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, for punitive damages, and for costs in excess of $75,000 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT II: STRICT LIABILITY – DEFECTIVE DESIGN

98. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

99. The pelvic mesh product at issue herein, the Gynecare TVT-O device, was designed, marketed, manufactured and distributed by Defendants and was defective and not reasonably safe due to its improper, inadequate, and defective design.

100. Defendants designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the Pelvic Mesh Product at issue herein and Plaintiff was an expected user or consumer of the mesh product.

101. Defendants' Pelvic Mesh Products, including the TVT-O Pelvic Mesh Product at issue in this case, were defectively and improperly designed, rendering the products deficient and unreasonably dangerous and hazardous to Plaintiff.

102. The TVT-O Pelvic Mesh Product at issue herein that was implanted in Plaintiff was conveyed in a condition not contemplated by reasonable persons among those considered expected users or consumers of the pelvic mesh product, like Plaintiff.

103. The TVT-O Pelvic Mesh Product at issue herein that was implanted in Plaintiff was, at the time conveyed, not in conformity with the generally recognized state of the art applicable to the safety of the product at the time the product was designed, manufactured, packaged, labeled and/or sold. There were also safer alternative designs for the device.

104. The TVT-O Pelvic Mesh Product that was implanted in Plaintiff was not reasonably safe for its intended use and was defective as described herein with respect to its design. The TVT-O Pelvic Mesh Product's design defects include, but are not limited to, the following:

a. The use of polypropylene in the TVT-O and the foreseeable adverse tissue reactions, host defense response, and immune reactions that result from such material leading to ongoing degradation of the mesh, shrinkage, perpetual scarification as the mesh degrades all of which have potential to produce adverse reactions and permanent injuries including but not limited to painful recurrent erosions, direct muscle and soft tissue injury, nerve entrapment or irritation of adjacent nerves, and associated intractable neuropathic pain and myofascial pain;

b. The design of the TVT-O to be inserted into and through an area of the body that is blood vessel rich, nerve dense, and bacteria laden leading to excessive blood loss and vascular damage, permanent nerve injury and associated chronic, intractable neuropathic pain, contaminated permanently-implanted mesh causing chronic infections, subclinical infections and biofilms, enhanced chronic inflammatory response, chronic wound healing with tissue destruction, as well as numerous other adverse reactions and serious and permanent injuries without producing any additional therapeutic benefit when compared to other surgical treatment options for SUI;

c. The design of the TVT-O to be inserted into and through the obturator internus and groin muscles produces a foreseeable risk of acute and chronic myofascial pain, muscle spasm, and/or neuralgia or neuropathy of the obturator and pudendal nerves;

d. The design of the TVT-O to be inserted into and through the obturator internus and groin muscles produces a foreseeable risk of obturator neuralgia that may present acutely or months to years after implantation;

e. The design of the TVT-O to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries without producing any additional therapeutic benefit when compared to other surgical treatment options for SUI;

f. Biomechanical issues with the design of the TVT-O, including, but not limited to, the propensity of the TVT-O mesh to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in serious and permanent injury to the soft tissues and muscles of the pelvic floor without producing any additional therapeutic benefit when compared to other surgical treatment options for SUI;

g. The use and design of arms and anchors in the Pelvic Mesh Product at issue herein, which, when placed in the women, such as Plaintiff, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

h. The use and design of arms and anchors in the Pelvic Mesh Product at issue herein, which, when placed in the women, such as Plaintiff, cause spasm of the obturator muscles which can aggravate, irritate, or inflate surrounding nerves, such as the obturator nerve and pudendal nerve;

i. The propensity of the Pelvic Mesh Product at issue herein for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

j. The inelasticity of the TVT-O mesh, causing the products to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g. intercourse, defecation, or walking) without providing any additional therapeutic benefit when compared to other surgical treatment options for SUI:

k. The propensity of the TVT-O mesh to degradation or fragment over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

l. The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

m. The propensity of the product to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

n. The hardening of the Pelvic Mesh Product at issue herein in the body;

o. The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions that are unique to polypropylene without providing any additional therapeutic benefit when compared to other non-polypropylene surgical treatment options for SUI; and

o. The use of polypropylene material in the Pelvic Mesh Product at issue herein and the failure to provide adequate instructions for use ("IFU") and training.

105. As designed, Defendants' Pelvic Mesh Products, including the TVT-O Pelvic Mesh Product at issue in this case, were and are inherently dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and do not meet or perform to the expectations of patients and their healthcare providers.

106. Defendants' Pelvic Mesh Products, including the TVT-O Pelvic Mesh Product at issue in this case, create risks to the health and safety of the patients that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the Pelvic Mesh Products

107. Defendants' Pelvic Mesh Products, including the TVT-O Pelvic Mesh Product at issue in this case, are not reasonably safe and so likely to be harmful to users that a reasonable person who had actual knowledge of their potential for producing injury would conclude that it should not have been marketed.

108. Defendants' Pelvic Mesh Products, including the TVT-O Pelvic Mesh Product at issue in this case, are dangerous beyond that which would be contemplated by an ordinary person, doctor, or patient with the ordinary knowledge common to the community as to its characteristics.

109. Defendants have intentionally and recklessly designed, marketed, labeled, sold, and distributed their Pelvic Mesh Products (including the TVT-O Pelvic Mesh Product at issue in this case) with wanton and willful disregard for the rights and health of Plaintiff, and with malice, placing their economic interests above the health and safety of Plaintiff.

110. At all relevant times, safer, alternative designs to the TVT-O existed which were technically and economically feasible and that in reasonable probability would have prevented or significantly reduced the risk of Plaintiff's injuries.

111. First, there were designs containing no synthetic, polymer-based sling material, such as the Burch Procedure colposuspension with delayed absorbable sutures, autologous fascia slings, and an allograft sling using a product like Repliform or other biological matrix; said slings would have been more biologically compatible with human tissue and would have therefore prevented the foreign body immune response that promotes degradation of the pelvic tissue and other complications. Second, there were sling designs constructed with less polypropylene such as Ultrapro, a retropubic mini-sling, such as the TFS device from TFS Surgical; said slings, by utilizing less polypropylene, would have ameliorated the foreign body immune response that promotes degradation of the pelvic tissue and other complications described herein. Third, there were retropubic slings designs which, by virtue of a design that eliminates trocar needle passage through the obturator internus muscle, would have prevented or significantly reduced the risk of obturator neuralgia and its related and/or consequential symptoms and effects. Fourth, there were retropubic sling or retropubic mini-sling designs comprised of a polymer-based alternative to polypropylene, such as Polyvinylidene fluoride (PVDF), a material which has greater biostability and biocompatibility than polypropylene, which, in addition to its design advantages previously discussed, would have prevented the level of foreign body immune response that promotes degradation of the pelvic tissue and other complications described herein. Finally, there were transobturator sling designs comprised of PVDF, which while using a transobturator approach would have prevented the level of foreign body immune response that promotes degradation of the pelvic tissue and other complications described herein.

112. With respect to Plaintiff in particular, flaws with the TVT-O design, including but not limited to the use of polypropylene mesh in the TVT-O, the weight and pore size of the polypropylene mesh used in the TVT-O device, and the transobturator design of the device[1], caused and created chronic inflammation and chronic foreign body reaction inside of Plaintiff, as well entrapment, aggravation, irritation and compression of Plaintiff's obturator, pudendal, and/or ilioinguinal nerves, which in turn damaged and aggravated the surrounding soft tissues. As a direct and proximate result of these design flaws, Plaintiff has suffered and in all reasonable probability will continue to suffer from dyspareunia, vulvodynia, nerve pain/irritation, groin pain, thigh pain, pelvic pain, extrapelvic pain, depression, and recurrent prolapse/incontinence, as well as other symptoms and damages, including severe and permanent pain, suffering, disability, impairment of mobility, impairment of sexual function, impairment of bowel and bladder function, subsequent surgical removal of the mesh, loss of enjoyment of life, and economic damages.

113. Plaintiff did not suffer from said injuries prior to implantation of the TVT-O Pelvic Mesh Product, and upon information and belief would not have suffered these injuries absent implantation of the TVT-O Pelvic Mesh Product. Plaintiff believed the TVT-O Pelvic Mesh Product would address her stress urinary incontinence, and did not know—nor did she have any reason to know, based upon the information provided to her and provided to her implanting physician regarding the risks of the TVT-O Pelvic Mesh Product, that she would sustain the injuries from the TVT-O Pelvic Mesh Product described herein.

[1] As stated previously, the transobturator design of the TVT-O to be inserted into and through the obturator internus and groin muscles produces a foreseeable risk of acute and chronic myofascial pain, muscle spasm, and/or neuralgia or neuropathy of the obturator and pudendal nerves.

114. As a direct and proximate result of the wrongful acts and omissions of Defendants, Plaintiff suffered severe injuries, emotional distress, and economic damages for which she now seeks compensation.

115. By reason of the foregoing, Plaintiff has damages in an amount in excess of the jurisdiction limits of all the lower courts which would have had jurisdiction.

116. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, for punitive damages, and for costs in excess of $75,000 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT III: NEGLIGENCE

117. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if each were set forth fully and completely herein.

118. Defendants had a duty to exercise reasonable care in the design, research, manufacture, marketing, testing, advertisement, supply, promotion, packaging, sale, and distribution of the Pelvic Mesh Products, including the TVT-O Pelvic Mesh Product at issue in this case.

119. Defendants breached their duty of care to Plaintiff in the design and marketing of the Pelvic Mesh Products, including the TVT-O Pelvic Mesh Product at issue in this case, by and for the reasons articulated in Counts I (Failure to Warn) and Counts II (Defective Design), respectively.

120. Defendants further breached their duty of care in the testing of their Pelvic Mesh Products, including the TVT-O Pelvic Mesh Product at issue in this case, by failing to conduct adequate testing to ensure that the Pelvic Mesh Products were reasonably safe for implantation in the female pelvic area prior to releasing the Pelvic Mesh Products into the market, failing to

conduct post-launch testing following adverse findings in the scientific and medical literature, and by failing to conduct post-launch testing to investigate and evaluate reports in the FDA adverse event databases for their potential significance for Defendants' Pelvic Mesh Products, including the TVT-O Pelvic Mesh Product at issue in this case.

121. Defendants breached the duty to take all reasonable steps necessary to design, market, test, and sell products that were not defective or unreasonably dangerous to consumers and users of the products, including Plaintiff herein. Defendants were negligent in failing to use reasonable care as described herein in designing, marketing, labeling, packaging and selling the TVT-O Pelvic Mesh Product at issue herein. Defendants breached the aforementioned duty by, among other things:

a. Failing to design the TVT-O Pelvic Mesh Product at issue herein so as to avoid an unreasonable risk of harm to women in whom the Pelvic Mesh Product at issue herein was implanted, including Plaintiff;

b. Failing to manufacture the TVT-O Pelvic Mesh Product at issue herein so as to avoid an unreasonable risk of harm to women in whom the Pelvic Mesh Product at issue herein was implanted, including Plaintiff;

c. Failing to use reasonable care in the testing of the TVT-O Pelvic Mesh Product at issue herein so as to avoid an unreasonable risk of harm to women in whom the TVT-O Pelvic Mesh Product at issue herein was implanted, including Plaintiff;

d. Failing to use reasonable care in inspecting the TVT-O Pelvic Mesh Product at issue herein so as to avoid an unreasonable risk of harm to women in

whom the Pelvic Mesh Product at issue herein was implanted, including Plaintiff;

e. Failing to use reasonable care in the training and instruction to physicians for the safe use of the TVT-O Pelvic Mesh Product at issue herein;

f. Failing to use reasonable care in studying the TVT-O Pelvic Mesh Product at issue herein to evaluate its safety and to determine the nature, magnitude, and frequency of serious, life threatening complications that were known or knowable; and

g. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the TVT-O Pelvic Mesh Product at issue herein.

122. The reasons that Defendants' negligence caused the TVT-O Pelvic Mesh Product at issue herein to be unreasonably dangerous and defective include, but are not limited to:

a. The use of polypropylene and/or collagen material in the TVT-O Pelvic Mesh Product at issue herein and the immune reaction that results from such material, causing adverse reactions and injuries;

b. The design of the TVT-O Pelvic Mesh Product at issue herein to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. The design of the TVT-O Pelvic Mesh Product at issue herein to be inserted into and through the obturator internus and groin muscles, placing it in

proximity to the obturator nerve and causing muscle spasms which can irritate and/or damage the obturator and pudendal nerves;

d. Biomechanical issues with the design of the TVT-O Pelvic Mesh Product at issue herein, including, but not limited to, the propensity of the TVT-O Pelvic Mesh Product at issue herein to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

e. The use and design of the TVT-O Pelvic Mesh Product at issue herein, which, when placed in the women, such as Plaintiff, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

f. The propensity of the TVT-O Pelvic Mesh Product at issue herein for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

g. The inelasticity of the TVT-O Pelvic Mesh Product at issue herein, causing it to be improperly mated to the delicate and sensitive areas of the pelvis where it is implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

h. The propensity of the TVT-O Pelvic Mesh Product at issue herein for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

i. The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

j. The propensity of the product to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

k. The adverse tissue reactions caused by the product, which are causally related to infection, as the polypropylene is a foreign material; and

l. The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

123. Defendants also negligently failed to warn or instruct Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. The TVT-O Pelvic Mesh Product's propensities to contract, retract, and/or shrink inside the body;

b. The TVT-O Pelvic Mesh Product's propensities for degradation, fragmentation and/or creep;

c. The TVT-O Pelvic Mesh Product's inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the TVT-O Pelvic Mesh Product at issue herein;

f. The risk of chronic infections resulting from the TVT-O Pelvic Mesh Product at issue herein;

g. The risk of permanent vaginal or pelvic scarring as a result of the TVT-O Pelvic Mesh Product at issue herein;

h. The risk of recurrent, intractable groin pain, pelvic pain, extrapelvic pain, and other pain resulting from the TVT-O Pelvic Mesh Product at issue herein;

i. The need for corrective or revision surgery to adjust or remove the TVT-O Pelvic Mesh Product at issue herein;

j. The severity of complications that could arise as a result of implantation of the TVT-O Pelvic Mesh Product at issue herein including pudendal neuralgia, obturator neuralgia, ilioinguinal neuralgia, and permanent nerve damage;

k. The hazards associated with the TVT-O Pelvic Mesh Product at issue herein;

l. The TVT-O Pelvic Mesh Product's defects described herein;

m. Treatment of stress urinary incontinence with the TVT-O Pelvic Mesh Product at issue herein is no more effective than feasible available alternatives;

n. Treatment of stress urinary incontinence with the TVT-O Pelvic Mesh Product at issue herein exposes patients to greater risk than feasible available alternatives;

o. Treatment of stress urinary incontinence with the TVT-O Pelvic Mesh Product at issue herein makes future surgical repair more difficult than feasible available alternatives;

p. Use of the TVT-O Pelvic Mesh Product at issue herein puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. Removal of the TVT-O Pelvic Mesh Product at issue herein due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. Complete removal of the TVT-O Pelvic Mesh Product at issue herein may not be possible and may not result in complete resolution of the complications, including pain.

124. As a direct and proximate result of the wrongful acts and omissions of Defendants, Plaintiff suffered severe injuries, emotional distress, and economic damages for which she now seeks compensation.

125. By reason of the foregoing, Plaintiff has damages in an amount in excess of the jurisdiction limits of all the lower courts which would have had jurisdiction.

126. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, for punitive damages, and for costs in excess of $75,000 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

DAMAGES

127. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if each were set forth fully and completely herein.

128. As a direct and proximate cause of having the Gynecare TVT-O sling implanted in her, Plaintiff Karen Richards has incurred and will incur in the future significant damages, including but not limited to:

a. Medical expenses sustained in the past;

b. Physical pain and suffering sustained in the past;

c. Mental anguish and emotional distress sustained in the past;

d. Physical disfigurement sustained in the past;

e. Physical impairment sustained in the past;

f. Loss of earning capacity sustained in the past;

g. Medical expenses which, in all reasonable probability, she will incur in the future;

h. Physical pain and suffering which, in all reasonable probability, she will incur in the future;

i. Mental anguish and emotional distress which, in all reasonable probability, she will incur in the future;

j. Physical disfigurement which, in all reasonable probability, she will incur in the future;

k. Physical impairment which, in all reasonable probability, she will incur in the future; and

l. Loss of earning capacity which, in all reasonable probability, she will incur in the future.

Request for Exemplary Damages

129. Defendants had knowledge of or should have had knowledge of, and/or were in possession of evidence demonstrating that the Pelvic Mesh Product at issue was defective and unreasonably dangerous and/or was an inappropriate choice for treatment of Plaintiff's SUI. Despite this knowledge, Defendants failed to, among other purposeful acts, inform or warn of the

dangers, establish and maintain an adequate quality and post-market or post-implant surveillance system, and/or recall the Pelvic Mesh Product.

130. The actions and omissions committed by Defendants and further outlined in Counts I, II, and III above demonstrate a grossly negligent disregard for the rights of others, the public, and Plaintiff, for which the law allows the imposition of exemplary damages. Defendants' actions and omissions, when viewed objectively from Defendants' standpoint at the time of same, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of this risk, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others, including Plaintiff.

131. Plaintiff therefore requests to assert a claim for exemplary damages in an amount that would punish Defendants for their conduct while deterring other manufacturers from engaging in such misconduct in the future.

DISCOVERY RULE AND TOLLING

132. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

133. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

134. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiff had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

135. Despite diligent investigation by Plaintiff into the cause of her injuries, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages and their relationship to the Product was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

136. The running of the statute of limitations in this cause is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiff and her healthcare providers of the true risks associated with the Product.

137. As a result of Defendants' fraudulent concealment, Plaintiff and her healthcare providers were unaware, and could not have known or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of Defendants.

DEMAND FOR JURY TRIAL

138. Plaintiff respectfully demands a jury trial in this action.

CONCLUSION AND PRAYER

WHEREFORE, Plaintiff demands judgment jointly and severally against the Defendants and for all causes of action alleged above and requests damages.

Date: July 28, 2021

Respectfully submitted,

/s/ Laura J. Baughman
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